Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12698

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

12698

COMPLAINT / INJURY REPORT

1. COMPLAINT NUMBER: CIN-7675

2. DATE OF COMPLAINT (Month / Day / Year): 11/7/97

3. FORM OF COMPLAINT
a.
(1) [X] TELEPHONE
(2) [ ] LETTER
(3) [ ] VISIT

4. SOURCE OF COMPLAINT
a.
(1) [X] CONSUMER (3) [ ] TRADE SOURCE
(2) [ ] GOVERNMENT (4) [ ] OTHER
[ ] L [ ] S [ ] F (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
a. NAME AND ADDRESS (Include ZIP Code): [redacted]
b. AREA CODE AND TELEPHONE NUMBER
HOME [redacted]
WORK ( )

6. COMPLAINT OR INJURY
a. DESCRIPTION OF COMPLAINT / INJURY
IMMEDIATELY AFTER CONSUMING PRODUCT, MS. [redacted] SUFFERED FROM DIZZINESS, NAUSEA & HEART BEAT IRREGULARITIES. ONCE SHE DID NOT INGEST PRODUCT SHE FELT FINE.

b. DOES COMPLAINANT EXPECT ADDITIONAL FDA CONTACT?
(1) [ ] NO (2) [X] YES
(If "Yes" Explain in Remarks)

7. INJURY OR ILLNESS RESULTED
(1) [ ] NO
(2) [X] YES *
*(If "yes" complete items a through d)

a. EIB (HFC - 161) NOTIFIED
(1) [X] NO
(2) [ ] YES
DATE:

b. TYPE SYMPTOMS — ONSET (HR.)
(1) [ ] VOMITING
(2) [X] NAUSEA — IMM.
(3) [ ] DIARRHEA
(4) [ ] FEVER
(5) [ ] SKIN/EYE IRR.
(6) [ ] HEADACHE
(7) [X] OTHER — IMM.
DIZZINESS, ARYTHMIA

c. ATTENDING HEALTH PROFESSIONAL?
(1) [ ] NO (2) [X] YES
(If "Yes" give name, address, and phone number)
[redacted]

d. HOSPITALIZATION REQUIRED?
(1) [X] NO (2) [ ] YES
(If "Yes" give name, address, phone number and dates)

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8. PRODUCT AND LABELING
a. BRAND NAME: HERBAL LIFE
b. PRODUCT NAME: ORIGINAL GREEN
c. SIZE AND PACKAGE TYPE: 120 TABS / PLASTIC BOTTLE
d. NAME AND LOCATION OF STORE WHERE PURCHASED: [redacted]
e. PACKAGE CODE / SERIAL NUMBER / ETC.
LOT #: 071603
EXP. / USE BY DATE:
f. DATE PURCHASED: ~ SEPT 20, '97
g. PRODUCT USED (If "Yes" enter date) (1) [ ] NO (2) [X] YES
Date: 9/20/97
h. AMT. REMAINING: 1 FULL BOTTLE

9. MANUFACTURER / DISTRIBUTOR OF PRODUCT
a. HOME DISTRICT: MINN LOS-DO
b. C.F. NO.: 2027832
c. NAME AND LOCATION OF FIRM (Include ZIP Code)
HERBAL LIFE INTERNAT'L LOS ANGELES, CA 90080-0210
d. IMPORT PRODUCT
(1) [X] NO
(2) [ ] YES

10. EVALUATION AND DISPOSITION
a. PROBLEM KEY WORD
(1) CODE: PX
(2) DESCRIPTION: DIZZINESS
b. EVALUATION
(1) [ ] NOT AN FDA OBLIGATION
(2) [ ] OBLIGATION, NO VIOLATION
(3) [X] FDA ACTION INDICATED
(4) [ ] INSUFFICIENT INFORMATION UNABLE TO EVALUATE

b. DISPOSITION
(1) [ ] IMMEDIATE FOLLOW-UP
(2) [ ] F / U NEXT EI
(3) [ ] CLOSED WITHOUT FURTHER INVESTIGATION
(4) [ ] REFERRED TO OTHER FEDERAL AGENCY (Closes File)
(5) [ ] REFERRED TO STATE / LOCAL AGENCY (Closes File)
(6) [X] REFERRED TO OTHER FDA LOS DISTRICT
(7) [ ] REFERRED TO OCI

11. PRODUCT CODE: 54CC09

12. INFORMATION COPIES TO:
[ ] HFM-660 [ ] HFZ-343
[ ] HFD-730 [ ] HFC-161
[ ] HFV-210 [X] HFS-635
[ ] OTHER

13. REMARKS MS. [redacted] FORWARDED INFO. TO [redacted] MS. [redacted] TOOK PRODUCT TO LOSE WEIGHT - PRODUCT DOES INDICATE HOW MUCH MA HUANG IS IN IT.

14. NAME AND TITLE OF DISPOSITION OFFICIAL
DIAD. DIRECT, ACCC

15. DATE: 11/7/97

FORM FDA 2516 (1/96)

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* U.S. GPO: 1996-404-897/41020

Adverse Reaction Information Form A

Complaint Number: CIN-7675 Investigator: DCR

Consumer Information

Date of Report: 03/17/98 (MM/DD/YY)

Initial Report Source: ☒ORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted] Gender: ☒F ☐M Age: 53

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other _____ ☐9-Unknown

Information on Adverse Reaction

Date of Adverse Reaction: 9/26/97
Previous Reaction to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. (home), restaurant, office):

Describe the adverse event: (including symptoms and the time lapse from using product to onset of symptoms): N/ausea, dizziness & arythemia - immed. Constipation < 24 hrs
How long did the symptoms last? till use was discontinued
Give the circumstances of exposure (e.g., dose, route of exposure, frequency, etc.). 9 tablets of the suspect diet taken per day. Approx 29 tablets + a protein drink 3X/day were taken as part of a weight loss pgm.
List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: ① medicine ② Premerin ③ Percocet. Diet Supplements - see *
Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒Not Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: [redacted] MD

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify) _____

What medical tests were performed and what were the results? None

What was the medical diagnosis?
What treatment(s) was given (e.g., drugs, other)?

Were there any preexisting condition(s)/treatment(s)? Allergic to Biaxin, Penicillin & Flagyl
(If YES, list them including allergies, and chronic diseases): ☒Yes ☐No No food allergies

Product Category

1. Adverse reaction to:
☐**Medical Food** (under medical supervision) ☐**Infant Formula**
☒**Dietary Supplement** (a vitamin; an essential mineral; a protein, a herb or similar nutritional substances including botanicals such as ginseng and yohimbe, amino acids, extracts from animal glands; garlic extract, fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
☐**Other** (traditional food) _____

Other Product Problems
2. ☐Foreign Object (specify): _____
3. ☐Other (specify): _____

* ① Original Green ④ Original Yellow
② Beigh ⑤ Herbal Loss
③ Celuloss ⑥ Protein drink

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Information on Suspected/Alleged Product

Give the product name (including dose/serving size, duration of use, and reason for taking):
Herbal Life - Original Green
Taking 9 pills / day for several days

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown

If a particular ingredient is suspected of contributing to the reaction, please indicate the appropriate category below:

☐ [illegible]partame
☐ [illegible]psodium Glutamate
☐ [illegible]ite
☒Other ephedrin
☐Unknown

☐Color Additive (please specify) _____

Product Label Available: ☐Yes ☒No ☐Unknown Product Sample Available: ☐Yes ☒No ☐Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☐Yes ☒No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☒No

Did the adverse reaction result in a congenital anomaly: ☐Yes ☒No

Ms. [redacted] states that since going off the weight management pgm - she has entered into a state of depression

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